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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,967	02/25/2002	Roger Dahl	P-9367	7022
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MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,967

Applicant(s)

DAHL, ROGER

Examiner

Kristen Mullen (formerly
Droesch)

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/25/03 (IDS).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/25/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 24 is objected to because of the following informalities: the second instance of "the second phase" on line 4 should be changed to --the second lead--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 10 recites the limitation "the third electrode" in lines 2-3 respectively.

There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Min et al. (5,690,686).

Regarding claim 1, Min et al. shows a method for defibrillating a heart, comprising placing a first electrode (23) into electrical contact with a first portion of the heart; placing a second electrode (8) into electrical contact with a second portion of the heart; and transmitting an electrical pulse between the first electrode and the second electrode in response to a determination that a cardiac event is detected (Col. 2, lines 36-40; Col. 8, lines 34-46; Fig. 1).

With respect to claim 11, Min et al. shows an apparatus comprising means (15) for placing a first electrode (23) into electrical contact with a first portion of the heart; means (6) for placing a second electrode (8) into electrical contact with a second portion of the heart; and means for transmitting an electrical pulse between the first electrode and the second electrode in response to a determination that a cardiac event is detected (Col. 2, lines 36-40; Col. 8, lines 34-46; Fig. 1).

Regarding claims 2, and 12, Min et al. shows the method and means for placing the first electrode (23) into electrical contact with the first portion of the heart further comprises the

Art Unit: 3762

method and means (15) for placing the first electrode (23) into electrical contact with a wall of a right atrium of the heart (Fig. 1).

With respect to claims 3, and 13, Min et al. shows the method and means (6) for placing the second electrode (8) into electrical contact with the second portion of the heart further comprises the method and means for placing the second electrode (8) into electrical contact with a wall of an oblique vein (CS) (Fig. 1).

Regarding claims 4, and 14, Min et al. shows the method and means for transmitting the electrical pulse further comprises the method and means for transmitting the electrical pulse between the first electrode and the second electrode in response to a determination that atrial fibrillation is detected (Col. 2, lines 36-40).

With respect to claims 5-6, and 15-16, Min et al. shows the method and means for transmitting the electrical pulse further comprises the method and means for transmitting a uniphasic or biphasic electrical pulse between the first electrode and the second electrode (Col. 9, lines 22-28).

With respect to claims 7, and 17, Min et al. shows the method and means (16) for placing a third electrode (20) into electrical contact with a wall of a right ventricle of the heart; and transmitting an electrical pulse between the third electrode and at least one of the first and second electrodes if the heart is experiencing ventricular fibrillation (Col. 8, lines 34-46).

Regarding claim 8, Min et al. shows the method and means for sensing the heart for ventricular fibrillation (Col. 8, lines 34-46).

With respect to claims 9-10, and 19-20, Min et al. shows the method and means for transmitting the electrical pulse further comprises the method and means for transmitting a

Art Unit: 3762

uniphasic or biphasic electrical pulse between the third electrode and at least one of the first and second electrodes (Col. 8, lines 34-46; Col. 9, lines 22-28).

With respect to claim 21, Min et al. shows a medical device comprising a control unit (23, 234, 236) capable of outputting a defibrillating pulse; a first lead (15) having a proximal end portion coupled with the control unit and a first electrode (23) electrically coupled with the control unit and disposed distally from the proximal end portion of the first lead, wherein the first lead is capable of being routed through a venous system of a body such that the first electrode is electrically coupled with a wall of a right atrium of a heart; a second lead (6) having a proximal end portion coupled with the control unit and a second electrode (8) electrically coupled with the control unit and disposed distally from the proximal end portion of the second lead, wherein the second lead is capable of being routed through the venous system of the body such that the second electrode is electrically coupled with a wall of an oblique vein (CS) (Figs. 1,3).

Regarding claim 22, Min et al. shows the first lead (15) is *capable* of receiving the defibrillating pulse from the control unit and is capable of transmitting the defibrillating pulse to the heart via the first electrode (23); and the second lead (6) is *capable* of transmitting the defibrillating pulse, received by the second electrode (8) from the heart, to the control unit (Col. 2, lines 36-40; Col. 9, lines 22-28; Fig. 1)

With respect to claim 23, Min et al. shows the second lead is *capable* of receiving the defibrillating pulse from the control unit and is capable of transmitting the defibrillating pulse to the heart via the second electrode; and the first lead is *capable* of transmitting the defibrillating

Art Unit: 3762

pulse, received by the first electrode from the heart, to the control unit (Col. 2, lines 36-40; Col. 9, lines 22-28; Fig. 1)

Regarding claim 24, Min et al. shows the control unit is *capable* of outputting a biphasic defibrillation pulse having a first phase and a second phase, wherein the first phase is outputted to the first lead and the second phase is outputted to the second lead; the first lead is *capable* of receiving the first phase from the control unit and is *capable* of transmitting the first phase to the first electrode; the second lead is *capable* of receiving the second phase from the control unit and is *capable* of transmitting the second phase to the second electrode; the first lead is *capable* of transmitting the second phase, received by the first electrode from the heart, to the control unit; and the second lead is *capable* of transmitting the first phase, received by the second electrode from the heart, to the control unit (Col. 2, lines 36-40; Col. 9, lines 22-28)

Regarding claim 25, Min et al. shows at least one of the first lead and the second lead further comprises a sensing electrode (17, 21) electrically coupled with the control unit (212) and being *capable* of receiving an electrical stimulus corresponding to a heart rhythm; and the control unit is *capable* of receiving and processing the electrical stimulus (Fig. 3).

With respect to claim 26, Min et al. shows the first lead further comprises a third electrode (20) electrically coupled with the control unit, wherein the first lead (16) is capable of being routed through the venous system of the body such that the third electrode is electrically coupled with a wall of a right ventricle of the heart (Fig. 1).

Regarding claim 27, Min et al. shows the first lead is *capable* of receiving the defibrillation current from the control unit and is capable of transmitting the defibrillation current to the heart via the third electrode; and the first lead is *capable* of transmitting the defibrillation

Art Unit: 3762

current, received via the first electrode from the heart, to the control unit (Col. 8, lines 34-46; Col. 9, lines 22-28).

With respect to claim 28, Min et al. shows the first lead is *capable* of receiving the defibrillation current from the control unit and is capable of transmitting the defibrillation current to the heart via the third electrode; and the second lead is *capable* of transmitting the defibrillation current, received via the second electrode from the heart, to the control unit (Col. 8, lines 34-46; Col. 9, lines 22-28).

Regarding claim 29, Min et al. shows the first lead is *capable* of receiving the defibrillation current from the control unit and is capable of transmitting the defibrillation current to the heart via the third electrode; the second lead is *capable* of transmitting a first portion of the defibrillation current, received via the second electrode from the heart, to the control unit; and the first lead is capable of transmitting a second portion of the defibrillation current, received via the first electrode from the heart, to the control unit (Col. 8, lines 34-46; Col. 9, lines 22-28).

6. Claims 1-4, 7-8, 11-14, 17-18, 21-23, and 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Kroll (6,456,876).

Regarding claim 1, Kroll shows a method for defibrillating a heart, comprising placing a first electrode (38) into electrical contact with a first portion of the heart; placing a second electrode (48) into electrical contact with a second portion of the heart; and transmitting an electrical pulse between the first electrode and the second electrode in response to a determination that a cardiac event is detected (Col. 4, line 66-Col. 5, line 1).

With respect to claim 11, Kroll shows an apparatus comprising means (30) for placing a first electrode (38) into electrical contact with a first portion of the heart; means (46) for placing

Art Unit: 3762

a second electrode (48) into electrical contact with a second portion of the heart; and means for transmitting an electrical pulse between the first electrode and the second electrode in response to a determination that a cardiac event is detected (Col. 4, line 66-Col. 5, line 1).

Regarding claims 2, and 12, Kroll shows the method and means for placing the first electrode (38) into electrical contact with the first portion of the heart further comprises the method and means (30) for placing the first electrode (38) into electrical contact with a wall of a right atrium of the heart.

With respect to claims 3, and 13, Kroll shows the method and means (46) for placing the second electrode (48) into electrical contact with the second portion of the heart further comprises the method and means for placing the second electrode (48) into electrical contact with a wall of an oblique vein (CS).

Regarding claims 4, and 14, Kroll shows the method and means for transmitting the electrical pulse further comprises the method and means for transmitting the electrical pulse between the first electrode and the second electrode in response to a determination that atrial fibrillation is detected (step 150, Fig. 2) (Col. 4, line 66-Col. 5, line 1).

With respect to claims 7, and 17, Kroll shows the method and means for placing a third electrode (36) into electrical contact with a wall of a right ventricle of the heart; and transmitting an electrical pulse between the third electrode and at least one of the first and second electrodes if the heart is experiencing ventricular fibrillation (step 140, Fig. 2) (Col. 4, lines 57-65).

Regarding claim 8, Kroll shows the method and means for sensing the heart for ventricular fibrillation (step 140, Fig. 2).

With respect to claim 21, Kroll shows a medical device comprising a control unit (60, 130) capable of outputting a defibrillating pulse; a first lead (30) having a proximal end portion coupled with the control unit and a first electrode (38) electrically coupled with the control unit and disposed distally from the proximal end portion of the first lead, wherein the first lead is capable of being routed through a venous system of a body such that the first electrode is electrically coupled with a wall of a right atrium of a heart; a second (46) lead having a proximal end portion coupled with the control unit and a second electrode (48) electrically coupled with the control unit and disposed distally from the proximal end portion of the second lead, wherein the second lead is capable of being routed through the venous system of the body such that the second electrode is electrically coupled with a wall of an oblique vein (CS) (Fig. 1)..

Regarding claim 22, Kroll shows the first lead (30) is *capable* of receiving the defibrillating pulse from the control unit and is capable of transmitting the defibrillating pulse to the heart via the first electrode (38); and the second lead (46) is *capable* of transmitting the defibrillating pulse, received by the second electrode (48) from the heart, to the control unit (Col. 4, line 66-Col. 5, line 1).

With respect to claim 23, Kroll shows the second lead is *capable* of receiving the defibrillating pulse from the control unit and is capable of transmitting the defibrillating pulse to the heart via the second electrode; and the first lead is *capable* of transmitting the defibrillating pulse, received by the first electrode from the heart, to the control unit (Col. 4, line 66-Col. 5, line 1).

Regarding claim 25, Kroll shows at least one of the first lead and the second lead further comprises a sensing electrode (34, 32) electrically coupled with the control unit (60, 62) and being *capable* of receiving an electrical stimulus corresponding to a heart rhythm; and the control unit is *capable* of receiving and processing the electrical stimulus (Fig. 1).

With respect to claim 26, Kroll shows the first lead further comprises a third electrode (36) electrically coupled with the control unit, wherein the first lead is capable of being routed through the venous system of the body such that the third electrode is electrically coupled with a wall of a right ventricle of the heart (Fig. 1).

Regarding claim 27, Kroll shows the first lead is *capable* of receiving the defibrillation current from the control unit and is capable of transmitting the defibrillation current to the heart via the third electrode; and the first lead is *capable* of transmitting the defibrillation current, received via the first electrode from the heart, to the control unit (Col. 4, lines 57-65).

With respect to claim 28, Kroll shows the first lead is *capable* of receiving the defibrillation current from the control unit and is capable of transmitting the defibrillation current to the heart via the third electrode; and the second lead is *capable* of transmitting the defibrillation current, received via the second electrode from the heart, to the control unit (Col. 4, lines 57-65).

Regarding claim 29, Kroll shows the first lead is *capable* of receiving the defibrillation current from the control unit and is capable of transmitting the defibrillation current to the heart via the third electrode; the second lead is *capable* of transmitting a first portion of the defibrillation current, received via the second electrode from the heart, to the control unit; and

Art Unit: 3762

the first lead is capable of transmitting a second portion of the defibrillation current, received via the first electrode from the heart, to the control unit (Col. 4, lines 57-65).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5-6, 9-10, 15-16, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll (6,456,876) in view of Min et al. (5,690,686). Kroll is as explained before. Although Kroll fails to teach transmitting a uniphasic or biphasic electrical pulse between the first electrode and the second electrode and transmitting a uniphasic or biphasic electrical pulse between the third electrode and at least one of the first and second electrodes, attention is directed to Min et al. which teaches the transmission of biphasic or uniphasic electrical pulses between the first electrode and the second electrode, and between the third electrode and at least one of the first and second electrodes. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to transmit biphasic or uniphasic electrical pulses between the first electrode and the second electrode, and between the third electrode and at least one of the first and second electrodes, since applicant has not disclosed that these particular waveforms provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any waveform such as the waveform taught by Kroll.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sh. Revishvili et al. (6,449,506) shows a defibrillator having a right atrium, right ventricle and coronary sinus/vein electrode, where the defibrillation waveform is applied between the electrodes in three or five phase. Helland (6,658,289) shows a defibrillator having a right atrium, right ventricle and coronary sinus/vein electrode, where the defibrillation waveform is applied between the electrodes in various sequences and combinations. Ideker et al. (5,107,834) and Ideker et al (5,224,476) both show a defibrillator having a right atrium, right ventricle and coronary sinus/vein electrode, where the defibrillation waveform is applied between the electrodes in various sequences and combinations ; KenKnight et al. (5,978,705) shows a defibrillator having a right atrium, right ventricle and coronary sinus/vein electrode, where the defibrillation waveform is applied between the electrodes in an auxiliary pulse and a primary pulse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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